

111TH CONGRESS
1ST SESSION

H. R. 999

To amend the Federal Food, Drug, and Cosmetic Act to improve food safety.

IN THE HOUSE OF REPRESENTATIVES

FEBRUARY 11, 2009

Mr. ROSKAM (for himself and Mr. KIRK) introduced the following bill; which
was referred to the Committee on Energy and Commerce

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to
improve food safety.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Keeping America’s
5 Food Safe Act of 2009”.

6 **SEC. 2. CERTIFICATION OF PRIVATE LABORATORIES AND**
7 **SAMPLING SERVICES.**

8 (a) AMENDMENT.—Chapter IV of the Federal Food,
9 Drug, and Cosmetic Act (21 U.S.C. 341 et seq.) is amend-
10 ed by adding at the end the following:

1 **“SEC. 418. FOOD SAFETY LABORATORIES AND SAMPLING**
2 **SERVICES.**

3 “(a) DEFINITIONS.—In this section:

4 “(1) FOOD SAFETY LABORATORY.—The term
5 ‘food safety laboratory’ means an establishment that
6 analyzes or tests samples of imported food to ensure
7 the safety of such food.

8 “(2) SAMPLING SERVICE.—The term ‘sampling
9 service’ means an establishment that collects sam-
10 ples of an imported food.

11 “(b) CERTIFICATION REQUIREMENT.—

12 “(1) IN GENERAL.—Any entity that is a food
13 safety laboratory or a sampling service shall submit
14 to the Secretary an application for certification.
15 Upon review, the Secretary may grant or deny cer-
16 tification to the food safety laboratory or sampling
17 service.

18 “(2) CERTIFICATION STANDARDS.—The Sec-
19 retary shall establish criteria and methodologies for
20 the evaluation of an application for certification sub-
21 mitted under paragraph (1). Such criteria shall in-
22 clude the requirements that a food safety laboratory
23 or sampling service—

24 “(A) be accredited as being in compliance
25 with standards set by the International Organi-
26 zation for Standardization;

1 “(B) agree to permit the Secretary to con-
2 duct an inspection of the facilities of the food
3 safety laboratory or sampling service and the
4 procedures of such facilities before making a
5 certification determination;

6 “(C) agree to permit the Secretary to con-
7 duct routine audits of the facilities to ensure
8 ongoing compliance with accreditation and cer-
9 tification requirements;

10 “(D) submit with such application a fee es-
11 tablished by the Secretary in an amount suffi-
12 cient to cover the cost of application review, in-
13 cluding inspection; and

14 “(E) agree to submit to the Secretary, in
15 accordance with the process established, the re-
16 sults of tests conducted by such food safety lab-
17 oratory or sampling service on behalf of an im-
18 porter.

19 “(c) SUBMISSION OF TEST RESULTS.—The Sec-
20 retary shall establish a process by which a food safety lab-
21 oratory or sampling service certified under this section
22 shall submit to the Secretary the results of all tests con-
23 ducted by such food safety laboratory or sampling service
24 on behalf of an importer.

1 “(d) CERTIFICATION OF IMPORTERS FOR TESTING
2 AND SAMPLING OWN PRODUCTS.—An importer shall not
3 be federally certified for the purposes of analyzing, testing,
4 or sampling its own food products for import unless the
5 Secretary establishes a process under this section by which
6 an importer can become certified for such purposes.”.

7 (b) ENFORCEMENT.—Section 303(f) of the Federal
8 Food, Drug, and Cosmetic Act (21 U.S.C. 333(f)) is
9 amended—

10 (1) by redesignating paragraphs (5), (6), and
11 (7) as paragraphs (7), (8), and (9), respectively;

12 (2) by inserting after paragraph (4) the fol-
13 lowing:

14 “(5) An importer (as such term is used in section
15 418) shall be subject to a civil penalty in an amount not
16 to exceed \$1,000,000 if such importer knowingly engages
17 in the falsification of test results submitted to the Sec-
18 retary by a food safety laboratory or sampling service cer-
19 tified under section 418.

20 “(6) A food safety laboratory or sampling service cer-
21 tified under section 418 shall be subject to a civil penalty
22 in an amount not to exceed \$1,000,000 for knowingly sub-
23 mitting to the Secretary false test results under section
24 418.”.

1 (3) in paragraph (2)(C), by striking “paragraph
2 (5)(A)” and inserting “paragraph (7)(A)”;

3 (4) in paragraph (7), as so redesignated, by
4 striking “paragraph (1), (2), (3), or (4)” each place
5 it appears and inserting “paragraph (1), (2), (3),
6 (4), (5), or (6)”;

7 (5) in paragraph (8), as so redesignated, by
8 striking “paragraph (5)(A)” and inserting “para-
9 graph (7)(A)”;

10 (6) in paragraph (9), by striking “paragraph
11 (6)” each place it appears and inserting “paragraph
12 (8)”.

13 **SEC. 3. FOREIGN CERTIFICATION AND EQUIVALENCY.**

14 (a) AMENDMENT.—Chapter VIII of the Federal
15 Food, Drug, and Cosmetic Act (21 U.S.C. 381 et seq.)
16 is amended by adding at the end the following:

17 **“SEC. 805. CERTIFICATION OF FOOD IMPORTERS.**

18 “(a) IN GENERAL.—Not later than 2 years after the
19 date of enactment of this section, the Secretary shall es-
20 tablish a certification program in accordance with this sec-
21 tion to ensure that food imported into the United States
22 meets the food safety standards applied to food produced
23 in the United States.

24 “(b) CERTIFICATION STANDARD.—A foreign facility
25 or foreign country requesting a certification to import food

1 to the United States shall demonstrate, in a manner deter-
2 mined appropriate by the Secretary, that food produced
3 under the supervision of the foreign facility or foreign
4 country has met standards for food safety, inspection, la-
5 beling, and consumer protection that are at least equiva-
6 lent to standards applicable to food produced in the
7 United States. In determining whether standards are so
8 equivalent, the Secretary shall consider—

9 “(1) the potential for health, sanitary, environ-
10 mental, or other conditions within the foreign coun-
11 try involved to adversely affect the safety of food
12 products exported from such nation; and

13 “(2) how well the food safety programs of the
14 foreign country function to minimize any adverse ef-
15 fects on such safety.

16 “(c) REQUIREMENT OF CERTIFICATION FOR IMPORT-
17 ING.—

18 “(1) IN GENERAL.—Except as provided in para-
19 graph (2), no food shall be permitted entry into the
20 United States from a foreign facility in a foreign
21 country unless there is—

22 “(A) a certification for such facility in ef-
23 fect under subsection (d)(1); or

24 “(B) a certification for such country in ef-
25 fect under subsection (d)(2).

1 “(2) EQUIVALENCY DETERMINATION BY SEC-
2 RETARY.—Paragraph (1) does not apply if the Sec-
3 retary determines that the certification process de-
4 scribed in subsection (d) is not needed for the Sec-
5 retary’s evaluation of whether the facility’s or coun-
6 try’s standards for food safety, inspection, labeling,
7 and consumer protection are at least equivalent to
8 standards applicable to food produced in the United
9 States.

10 “(d) CERTIFICATION.—

11 “(1) FOREIGN FACILITY.—Each foreign facility
12 seeking to import food into the United States may
13 obtain a certification by the Secretary stating that
14 the facility maintains a program using reliable ana-
15 lytical methods to ensure compliance with all the
16 food safety standards described in subsection (a) to
17 import such food.

18 “(2) FOREIGN COUNTRY.—A foreign country
19 may obtain a certification by the Secretary stating
20 that—

21 “(A) the country has in effect and is en-
22 forcing food safety standards at least as protec-
23 tive of food safety as the standards applicable
24 to food in the United States; and

1 “(B) the country has a program in effect
2 to monitor and enforce its food safety standards
3 with respect to food being exported from such
4 country to the United States, ensuring that the
5 food products intended for export to the United
6 States are safe for human consumption, and
7 not adulterated or misbranded.

8 “(e) AGREEMENTS WITH FOREIGN NATIONS.—Any
9 certification of a foreign country under subsection (d)(2)
10 shall—

11 “(1) require the foreign country to promptly no-
12 tify the Secretary of any violations affecting the
13 safety of food products exported or intended for ex-
14 port to the United States;

15 “(2) provide for such activities (whether in the
16 foreign country or at the port of entry during impor-
17 tation) by the Secretary, including analysis, testing,
18 and sampling, at such stages in the growth or har-
19 vest of food, or in the processing or handling of food
20 products, as the Secretary considers appropriate to
21 ensure that the foreign country has in effect and is
22 enforcing food safety standards at least as protective
23 of food safety as the standards applicable to food in
24 the United States; and

1 “(3) provide for reciprocity with respect to the
2 treatment of food imports and exports between the
3 United States and the foreign country.

4 “(f) DOCUMENTATION.—The Secretary shall provide
5 to the Congress annual documentation demonstrating the
6 Secretary’s confidence in the standards of any foreign fa-
7 cility or country for which the Secretary has made a deter-
8 mination under paragraph (2) of subsection (c).

9 “(g) REVOCATION OF CERTIFICATION.—The Sec-
10 retary may, with respect to a foreign facility or foreign
11 country, revoke a certification under subsection (d) if—

12 “(1) food from the foreign facility or foreign
13 country is linked to an outbreak of human illness;

14 “(2) the Secretary determines that the foreign
15 facility or foreign country is no longer meeting the
16 requirements described in subsection (d); or

17 “(3) United States officials are not allowed to
18 conduct such audits and investigations as may be
19 necessary to carry out this section.

20 “(h) DURATION OF CERTIFICATION.—Each certifi-
21 cation under subsection (d) shall be for a period of not
22 more than 5 years.

23 “(i) INSPECTION; INDEPENDENT AUDITS.—

24 “(1) AUTHORIZATION.—In determining whether
25 to issue a certification under subsection (d) or re-

1 voke a certification under subsection (g), the Sec-
2 retary is authorized to—

3 “(A) inspect foreign facilities to ensure
4 compliance with the food safety standards de-
5 scribed in subsection (a); and

6 “(B) consider independent audits, product
7 test data, and other relevant information gen-
8 erated by the facility, importer, or foreign coun-
9 try involved.

10 “(2) RENEWAL OF CERTIFICATION.—The Sec-
11 retary shall audit foreign countries and foreign fa-
12 cilities at least every 5 years to ensure the continued
13 compliance with the standards set forth in this sec-
14 tion.

15 “(j) ENFORCEMENT.—The Secretary is authorized
16 to—

17 “(1) deny importation of food from any foreign
18 country that does not permit United States officials
19 to enter the foreign country to conduct such audits
20 and inspections as may be necessary to fulfill the re-
21 quirements of this section;

22 “(2) deny importation of food from any foreign
23 country or foreign facility that does not consent to
24 an investigation by the Secretary when food from
25 that foreign country or foreign facility is linked to

1 a food-borne illness outbreak or is otherwise found
2 to be adulterated or mislabeled; and

3 “(3) promulgate rules and regulations to carry
4 out the purposes of this section, including setting
5 terms and conditions for the destruction of products
6 that fail to meet the standards of this Act.

7 “(k) FOREIGN FACILITY.—In this section, the term
8 ‘foreign facility’ means a foreign facility (as defined in sec-
9 tion 415(b)(3)) that is required to be registered under sec-
10 tion 415.”.

11 (b) TRANSITIONAL PROGRAM.—Not later than 180
12 days after the date of enactment of this Act, the Secretary
13 shall promulgate regulations to establish a transitional
14 food safety import review program, with minimal disrup-
15 tion to commerce, that shall be in effect until the date
16 of implementation of the food import certification program
17 under section 805 of the Federal Food, Drug, and Cos-
18 metic Act, as added by subsection (a) of this section.

19 **SEC. 4. INFORMATION CLEARINGHOUSES.**

20 Chapter IV of the Federal Food, Drug, and Cosmetic
21 Act (21 U.S.C. 341 et seq.), as amended by section 2 of
22 this Act, is amended by adding at the end the following:

23 **“SEC. 419. INFORMATION CLEARINGHOUSES.**

24 “(a) WEBSITE ON FOOD SAFETY ISSUES.—

1 “(1) IN GENERAL.—The Secretary, in consulta-
2 tion with the Secretary of Agriculture, shall develop
3 and maintain a Website with public information
4 that—

5 “(A) provides information on Federal food
6 standards and best practice requirements for
7 food preparation;

8 “(B) assists health professionals to im-
9 prove their ability—

10 “(i) to diagnose and treat food-related
11 illness; and

12 “(ii) to advise individuals whose
13 health conditions place them at particular
14 risk; and

15 “(C) promotes the public awareness of food
16 safety issues.

17 “(2) RESOURCES.—The Secretary shall utilize
18 the resources of the Food and Drug Administration
19 and the Centers for Disease Control and Prevention
20 to carry out this subsection.

21 “(b) WEBSITE ON SCHOOL CURRICULA REGARDING
22 FOOD SAFETY.—The Secretary, in consultation with the
23 Secretary of Education, shall develop and maintain a
24 Website to provide the public with appropriate information

1 on developing school curriculum regarding food safety
2 issues.”.

3 **SEC. 5. WHISTLEBLOWER PROTECTION.**

4 Chapter IV of the Federal Food, Drug, and Cosmetic
5 Act (21 U.S.C. 341 et seq.), as amended by sections 2
6 and 4 of this Act, is amended by adding at the end the
7 following:

8 **“SEC. 420. WHISTLEBLOWER PROTECTION.**

9 “(a) PROHIBITION.—No employee or other person
10 may be harassed, prosecuted, held liable, or discriminated
11 against in any way because that person—

12 “(1) has commenced, caused to be commenced,
13 or is about to commence a proceeding, testified or is
14 about to testify at a proceeding, or assisted or par-
15 ticipated or is about to assist or participate in any
16 manner in such a proceeding or in any other action
17 to carry out the purposes, functions, or responsibil-
18 ities of this Act; or

19 “(2) is refusing to violate or assist in violation
20 of this Act.

21 “(b) PROCEDURES.—The process and procedures
22 with respect to prohibited discrimination under subsection
23 (a) shall be governed by the applicable provisions of sec-
24 tion 31105 of title 49, United States Code, unless the
25 party bringing an action under this subsection chooses al-

1 ternative dispute resolution procedures such as mediation
2 or arbitration.

3 “(c) BURDENS OF PROOF.—The legal burdens of
4 proof with respect to prohibited discrimination under sub-
5 section (a) shall be governed by the applicable provisions
6 of sections 1214 and 1221 of title 5, United States
7 Code.”.

8 **SEC. 6. REPORTABLE FOOD REGISTRY.**

9 (a) RESPONSIBLE PARTIES.—Paragraph (1) of sec-
10 tion 417(a) of the Federal Food, Drug, and Cosmetic Act
11 (21 U.S.C. 350f(a)) is amended to read as follows:

12 “(1) RESPONSIBLE PARTY.—The term ‘respon-
13 sible party’, with respect to an article of food, means
14 a person that—

15 “(A) submits the registration under section
16 415(a) for a food facility that is required to
17 register under section 415(a), at which such ar-
18 ticle of food is manufactured, processed,
19 packed, or held; or

20 “(B) is an establishment that analyzes or
21 tests samples of food for consumption in the
22 United States to ensure the safety of such
23 food.”.

24 (b) INDIVIDUAL ANALYSIS OR TEST.—Subsection (d)
25 of section 417 of the Federal Food, Drug, and Cosmetic

1 Act (21 U.S.C. 350f(d)) is amended by adding at the end
2 the following:

3 “(9) INDIVIDUAL ANALYSIS OR TEST.—If any
4 individual analysis or test of an article of food by a
5 responsible party produces a result suggesting that
6 the article is reportable food, the responsible party
7 shall send a notice within 24 hours to the Food and
8 Drug Administration containing the results of such
9 analysis or test for review consistent with subsection
10 (b)(2), irrespective of whether the party subse-
11 quently determines, based on additional analysis or
12 testing or other factors, that such article is not re-
13 portable food.”.

14 (c) CONFORMING AMENDMENTS.—Section 417 of the
15 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350f)
16 is amended—

17 (1) in subsection (e)(1), by striking “The reg-
18 istration” and inserting “In the case of a responsible
19 party described in subsection (a)(1)(A), the registra-
20 tion”; and

21 (2) in subsection (f)(2)(A), by striking “not re-
22 quired to register under section 415” and inserting
23 “not responsible parties”.

1 **SEC. 7. RECALL AUTHORITY.**

2 (a) PROHIBITION.—Section 301 of the Federal Food,
3 Drug, and Cosmetic Act (21 U.S.C. 331) is amended by
4 adding at the end the following:

5 “(oo) The violation of an order to recall food under
6 section 417A.”.

7 (b) RECALL AUTHORITY.—Chapter IV of the Federal
8 Food, Drug, and Cosmetic Act (21 U.S.C. 341 et seq.)
9 is amended by inserting after section 417 the following:

10 **“SEC. 417A. RECALL AUTHORITY.**

11 “(a) REQUEST TO INITIATE A RECALL.—The Sec-
12 retary may request an establishment to initiate a recall
13 of food when the Secretary makes each of the following
14 determinations:

15 “(1) The food has been distributed and pre-
16 sents a risk of illness or injury or gross consumer
17 deception.

18 “(2) The establishment has not initiated a re-
19 call of the food.

20 “(3) Action by the Secretary is necessary to
21 protect the public health.

22 “(b) ORDER.—If an establishment subject to a re-
23 quest under subsection (a) does not initiate a voluntary
24 recall of the food involved within 24 hours of receiving
25 such request, the Secretary may issue an order requiring
26 such establishment to conduct a recall of the food.

1 “(c) DEFINITION.—In this section, term ‘establish-
2 ment’ means an establishment required to be registered
3 under section 415.”.

4 **SEC. 8. AUTHORIZATION OF APPROPRIATIONS.**

5 There are authorized to be appropriated to carry out
6 this Act and the amendments made by this Act such sums
7 as may be necessary for each of fiscal years 2010 through
8 2014.

○